

Informed Consent for Cheek Cell Samples

TITLE OF STUDY: National Birth Defects Prevention Study

RESEARCHERS:

National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, and the Centers for Birth Defects Research and Prevention

PURPOSE:

Major birth defects occur in about three out of every 100 babies. The cause is unknown for most of these babies. Birth defects can be prevented only if these causes are understood. The Centers for Disease Control and Prevention (CDC) is doing a research study of babies who do and do not have birth defects to try to understand their causes. To help us to understand environmental and other causes of birth defects, you have already provided us with information through a questionnaire. To help us to understand more about the genetics of birth defects, we are collecting samples from the inside of the cheek from the child, and his/her mother and father.

PROCEDURES:

If you decide to take part in this study, we would like you to give us samples of cells from the inside of the cheek from the child, mother, and father. Samples are collected by brushing the inside of the cheek with a soft brush for 30 seconds. These samples will be used to study genes, which may play a role in why some babies have birth defects. They will only be used to study birth defects and for no other purpose. We have no plans to ever destroy these samples. In some cases, we cannot get reliable information from a sample. This doesn't happen very often. There can be a variety of reasons why this happens. Some possible reasons are too little material in the sample, the sample got contaminated during shipping or processing, or other reasons. If this happens, we will contact you and ask if you are willing to send another sample.

RISKS:

The possible physical risk of this procedure is for temporary, minor discomfort to the inside of the mouth. To protect your confidentiality, no names or other personal information will be attached to the samples.

BENEFITS:

There is no personal benefit to you for taking part in this study. The major benefit is that this study may result in a better understanding of the causes of birth defects. This information will be helpful to all individuals of childbearing age, or who may have children someday. We will share what we learn with other health professionals through medical publications. None of these publications will include information that could identify you or your child in any way.

CONFIDENTIALITY:

All information that we gather in this study will be kept private. This is assured under Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify you or

anyone else in this study. Records may be reviewed by officials checking on the quality of the research. This protection lasts forever (even after death) for any persons who were subjects in the research during any time the certificate was in effect. However, you should understand that the investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Cheek cell samples will be stored without your names but are linkable. Information about you may be shared with other participating sites and other researchers when and if it has been approved by research review committees. The shared data will not contain any information that could identify any individual. This information will be used only for the study of birth defects. If you would like a copy of the Certificate of Confidentiality for this project, please call _____ at _____ and it will be provided to you.

COSTS/COMPENSATION:

Parents who agree to provide cheek cell samples on themselves and their child will receive \$20.00 per family with the kit to provide for any expense or inconvenience. Each family will receive an additional \$20 when the kit is returned. CDC does not normally pay for medical treatment in the unlikely event of injury as a result of taking part in this study.

RIGHT TO REFUSE OR WITHDRAW:

Participation in all parts of this study is voluntary. You and your child are free to not take part in the study and you are free to withdraw from any or all parts of this study at any time without penalty or loss of benefits to you. If at any time in the future, you would like to have your interview information or cheek cell samples destroyed or removed from the study, please call _____ at _____.

LABORATORY RESULTS:

The studies that will be done on these samples are not meant to test the medical status of you or your child. Since all studies will be done in research labs, we do not plan to return to you the results of the studies. Research labs do not have the same quality control standards as clinical labs. Research labs may also use less expensive techniques, which can make the tests less reliable than those from a clinical lab. However, a few of these studies may have clinical importance. For any tests that have clinical importance, we will publish summarized results in the study newsletter. This newsletter is sent to all participants. You will be able to request your test results that may have clinical importance from your study center. Each parent may request results for the child and for herself or himself. One parent may not request results for the other. If you have questions about whether any genetic tests would be useful to you, we recommend that you consult your health care provider.

CONTROL and OWNERSHIP OF BIOLOGIC MATERIALS:

Some of the cheek cell samples will be studied shortly after they are collected. Most of the cheek cell samples will be stored in a specimen bank for studies in the future. Study researchers will have control over the stored samples unless you request that your sample be removed from storage.

COMMERCIAL VALUE OF BIOLOGIC MATERIALS:

We will not use the cheek cell samples collected from you for commercial purposes.

PARTICIPANT CONSENT:

I have read this consent form or had its contents explained to me. All of my questions have been satisfactorily answered.

SIGNATURES

Print Infant's name: _____

Parent: I have read this consent form or had its contents explained to me. All of my questions have been satisfactorily answered. I voluntarily agree to provide a cheek cell sample for my child.

Parent's Signature: _____
(Sign here if a sample is being sent from your child -- either parent may sign.)
Date: _____

Mother: I have read this consent form or had its contents explained to me. All of my questions have been satisfactorily answered. I voluntarily agree to provide a cheek cell sample.

Mother's Signature: _____
(Sign here if a sample is being sent from the mother.)
Date: _____

Signature of Parent/Legal Guardian of mother if mother is a minor:

Father: I have read this consent form or had its contents explained to me. All of my questions have been satisfactorily answered. I voluntarily agree to provide a cheek cell sample.

Father's Signature: _____
(Sign here if a sample is being sent from the father.)
Date: _____

Signature of Parent/Legal Guardian of father if father is a minor:

If you have any questions, please contact:

If you have questions about your rights as a subject in this research study, please call the Office of the Deputy Associate Director for Science for CDC at 1-800-584-8814, leave a message

including your name, phone number, and refer to protocol #2087, and someone will call you back as soon as possible.